PURPOSE OF MANUAL

The purpose of this manual is to provide our clients with information about the laboratory services available and to provide a guide for collecting and submitting specimens for analysis.

This ninth edition can also be accessed on the DHEC Internet web site.

MISSION

The Bureau of Laboratories, S.C. Department of Health and Environmental Control, formerly named the State Public Health Laboratory, is a multi-disciplinary, integrated source of diagnostic services including analytical support and consultation for physicians, private laboratories and county health departments. The Bureau of Laboratories is prepared to assist in any national public health emergency.

The mission of the Bureau of Laboratories is to provide laboratory-based health and environmental assessments for accurate diagnosis, prevention and surveillance of infectious and chronic diseases, congenital disorders and environmental hazards to reduce the incidence of illness and death and to improve the quality of life among the people of the state.

BUREAU ADDRESS

The Bureau of Laboratories is located in the James A. Hayne Building at 8231 Parklane Road, Columbia, South Carolina 29223, on the campus of the State Park Health Center. State Park is located between Highway 555 (Farrow Road), Parklane Road and the I-77 connector (Bull Street extension or S.C. I-277) two miles north of I-20 and 2 miles west of Columbia Mall. Using the Parklane Road Entrance, the Hayne Building is at the end of the first left turn.

HOURS OF BUSINESS

The official working hours are from 8:00 A.M. to 4:30 P.M. Monday through Friday.

Weekend and Holiday Testing

The laboratory maintains an ON-CALL Roster for all weekends and holidays. Individuals requesting information or services of an emergency nature can call the main number, 803-896-0800. This number transfers to the answering service who will contact the Director on call.

Emergency Response/ Disaster Preparedness:

As part of the DHEC's Emergency Preparedness Plan of Action for emergencies, the Bureau of Laboratories is equipped and staff trained to respond rapidly and effectively to a medical emergency natural disaster or Act of Bioterrism. If the emergency occurs outside of regular working hours, personnel will be called back or work overtime as needed to provide laboratory support.

SPECIMEN RECEIVING

Specimens transported by General Services' courier are placed in specially marked boxes and are picked up by lab staff from the Sims-Aycock complex between 5:00 and 5:30 AM Tuesday through Saturday. Specimens are picked up by laboratory staff on weekends and holiday periods exceeding 24 hours from the U.S. Post Office and DHEC at 2600 Bull Street. These are sorted and stored according to established protocol to be accessioned on the next working day.

Specimens sent by first class mail are delivered from the Sims-Aycock complex by DHEC courier at 9:00 AM Monday through Friday. Those with a Parklane Road address are picked up by Supply staff at 8:30 AM. The U.S. Post Office delivers at approximately 12:30 PM, Monday through Friday.

Specimens are accepted at the Hayne Building during business hours of 8:00 AM to 4:30 PM Monday through Friday, except for state holidays. Private couriers should call Specimen Management at 803-896-0898 to arrange for delivery at the back entrance of the Hayne Building. Private individuals delivering specimens must enter the building through the front entrance. The Protective Services Officer will assist them.

AFTER HOURS DELIVERY OF SPECIMENS

A depository is located on the loading dock at the rear of the building for after hour deliveries. This depository is a refrigerator primarily for animal heads. If the specimen should not be refrigerated or may break if dropped into the depository, special arrangements for delivery must be made with the laboratory section conducting the test. This person will notify the Protective Services Officer on duty that a delivery is expected.

CONTACT PERSONS AND PHONE NUMBERS

(Area Code 803)

ReportsLaboratory Request Forms/Mailing ContainersFacilities Maintenance (Laboratory Instrument Servi		896-0913
Bureau Chief	Arthur Wozniak, Dr.Ph	896-0801
Director, Microbiology Division	Jennifer Meredith, Ph.D.	896-0870
Director, Chemistry Division	Thomas M Hickey, Ph.D	896-0964
Director, Chemistry Division (Deputy)	John Reddic, Ph.D	896-9725
Director, Pathology Division	Marc S Busnardo, MD	896-0658
Director, Support Division		
Director, Logistics Division	David C Rivers	896-0923
Director, Office of Quality AssuranceRober	rta Bartholdi, MS MT(ASCP)	896-3897
Director, Office of Laboratory Safety	Connie Gray, MPH	896-0956

LABORATORY ACCREDITATION AND CERTIFICATION

CLINICAL TESTING - CLIA ID # 42D0658606 FORENSIC DRUG TESTING - CAP # 14209-01 INDUSTRIAL HYGIENE - AIHA # 100621 ENVIRONMENTAL LEAD - AIHA # 100621 DAIRY PRODUCTS - FDA # 45001

TESTING POLICIES

Persons Authorized To Order Tests

The Laboratory will accept clinical laboratory specimens for testing from physicians, health departments, and hospital laboratories, or as provided by South Carolina statues. These senders will be responsible for receiving, relating, interpreting, and/or distributing the data.

A clinical laboratory specimen is described as any material derived from the human body for the purpose of diagnosis, prevention, treatment or assessment for medical or legal purposes. Clinical laboratory specimens for drug-of-abuse testing from other sources (legal entities) will be accepted with prior approval of the appropriate Division Director or Bureau Chief. Inanimate substances and other samples submitted for examination (e.g., food samples, animal heads for rabies, veterinary specimens, etc) may be accepted from private citizens at the discretion of the Division Director or Section Supervisor or Bureau Chief.

Verification of Orally Ordered Tests

When additional tests are requested by telephone, the caller is asked to follow up with a written request on letterhead, or an additional laboratory request form for the test(s) requested. The written request should be sent to the attention of the Specimen Accessioning Section or to the Section Supervisor. The additional test(s) will not be performed until the written request is received. With time sensitive tests, the specimen may be tested immediately and the results held until the written request is received. In this case the caller may fax the request to the Laboratory. The caller should obtain the proper fax number at the time of their request. To process and test a specimen without a written request, the oral request is recorded in the telephone log of the area receiving the call: **Exception: No HIV tests will be performed without written request at the time of testing.** All specimens will be discarded if a written request is not received within seven working days

Requesting Repeat Testing On a Serology Specimen

To request a repeat serology test call Specimen Logistics, (803) 896-0898. Specimens are discarded after seven working days. A retest request must be made within that time period. Repeat testing on the same specimen may not always be feasible. The caller may be asked to briefly provide some patient clinical information and history to assist in determining the best approach. In some cases, a second (new) specimen for testing may be recommended. In other cases, the patient's clinical history may provide an explanation for the initial result, and retesting may not be necessary.

Specimens Referred for Testing To CDC

Laboratories wishing to send specimens directly to CDC should contact Diagnostic Microbiology Division, (803) 896-0965. The sender will be assigned a State Health Department number and will be asked to fax or mail to the Laboratory a copy of the information being sent. CDC forms are also available from the Laboratory.

Other Reference Laboratories

If a specimen is sent to a reference laboratory for initial, follow-up or verification testing by the Bureau of Laboratories, the sender will the notified that the specimen has been referred. The original result report from the reference laboratory is forwarded or faxed to the sender. A copy of the report is maintained by the laboratory.

STAT Testing

Requests received in the morning mail will be put in the day's run. The results will be telephoned to the requestor, followed by a hard copy report. If the request is for a test that will not be performed immediately, the requestor will be informed by telephone when the test will be performed and the result available.

Confirmatory Testing

When confirmatory tests are necessary, patient results are not released until all testing is completed.

Laboratory Specimens Sent To the Bureau of Laboratories in Error

Specimens sent to the laboratory in error will be returned to the sender as soon as possible.

Correction of Patient Information

If a sender wishes to have an error corrected which was made on the original request form i.e. name not spelled correctly by sender, the sender must send a written statement on letterhead to the Specimen Accessioning Section indicating both the incorrect information and the correct information. The patient's record will be updated to reflect the change and a corrected report will be mailed to the sender.

A mislabeled specimen may not be known until the laboratory is notified that a report is in error because no specimen was collected from that patient. If the laboratory records are in order (the report, request and specimen are identified with the same name), the report will be re-mailed with a disclaimer. The submitting facility will be requested to submit a specimen on the correct patient if it is known which patient should have been tested.

Premarital Testing

There is no premarital testing requirement to obtain a marriage license in South Carolina.

The Bureau of Laboratories has the required premarital forms from all states with premarital testing requirements. A signed form for the state named will be returned to the requesting facility along with the result report. Call 803-896-0801 for additional information.

States Requiring Pre-Marital Testing

F=Female

INDIANA Rubella (F)
MASSACHUSETTS Syphilis
MISSISSIPPI Syphilis

MONTANA Rubella (F), exemption granted by physician

OKLAHOMA Syphilis
DISTRICT OF COLUMBIA Syphilis
PUERTO RICO Syphilis

SPECIMEN REJECTION& DISCLAIMER CRITERIA

These are considered Universal rejections as they apply to all specimens submitted for testing. Specific Test related rejections are listed in the Alpha Test section and the collection procedures.

No Specimen Received

When a request form is received without a specimen, a computer inquiry is made to determine if the specimen has been received with another test request. If so, the specimen is obtained and aliquoted for all tests. If no specimen is found, the request form is numbered, processed, and reported "No specimen received."

No Request Form Received

If a specimen is received without a request form and the sender cannot be identified from the specimen label, the specimen will be held for seven days awaiting telephone inquiry or delayed receipt of form. After seven days the specimen is discarded.

No Name on Specimen

When a specimen is received without an identifying number or patient name, it WILL NOT be tested. An exception may be made for a specimen that cannot be recollected because of its unique anatomic source, collection method or time of collection. Examples include: CSF, peritoneal pleural and synovial fluids, autopsy, biopsy, or organ specimens, and specimens collected prior to the initiation of antimicrobial therapy.

No Name on Request Form

When a request form is received without a name, and there is no other identification on the form that matches the information on the specimen, the specimen will be reported as "No name on form."

No Test Requested

If the Test requested block is not marked on the request form and the sender is known, the specimen will be held and the sender notified by phone, fax or mail to send a corrected request form. When received, the specimen will be tested. If the test needed can be determined by the specimen container or test request form, i.e. OraSure, blood lead, or the test needed is written on the specimen label. The test will be added to the request form and the specimen processed as usual.

Other Missing Information

If other necessary information is missing, the specimen will be tested and the missing information will be requested by phone or by mail. The result will be held until the missing information is received.

Mismatched Information:

When the name on the request form and the specimen do not match, the specimen will not be tested .It will be reported as "Name on specimen differs from name on request form."

Partial Information Matches

When there is a partial name match and other data on the request form indicates it is most probably the same patient, (Patient ID or SS Number), the name on the tube is written on the request form, and the test is run and a disclaimer added to the report.

Specimen rejections, con't

Requesting Corrections

All requested changes to the request form by the sender must be documented on letterhead, dated and signed by the requestor. A returned copy of the original laboratory report requesting the missing information is acceptable to communicate changes needed as long as the sender states clearly what is needed, dates, and signs or photocopy the report.

Specimen Broken or Leaking in Transit

When a broken or leaking specimen is received, every attempt will be made to salvage it without compromising the integrity of the specimen. An exception is made for a Cytology slide that is broken (not crushed) and can be reconstructed, and for TB Culture of sterile body fluids.

Incorrect Specimen Received:

If the specimen received is incorrect for the test requested, a search is initiated to determine if the correct specimen was received with a request form for a different test. If the specimen is found, testing will be done. If the specimen is not found, the specimen is reported as "incorrect specimen received."

Unsatisfactory Specimens

The Bureau of Laboratories will not examine and will discard specimens which are received in unsatisfactory condition. The reasons for the rejection will be reported to the sender on the standard laboratory report form. Unsatisfactory conditions include but are not limited to:

Hemolyzed, chylous, or contaminated specimen,

Specimen received beyond the acceptable time for testing,

Specimen taken too soon or too late in the illness for the test requested,

Specimen was stored and shipped at improper temperature,

Specimen is nonviable, or decomposed

Specimen quantity insufficient

Specimens that have some degree of hemolysis, are icteric, or chylous, will be tested if the degree of hemolysis or lipemia does not interfere with the examination. The undesirable condition will be indicated on the report form.

RESULTS REPORTING POLICIES

All laboratory reports generated are considered confidential information. The reports will be released only to authorized persons. Electronic transfer of results is available to DHEC county health departments and some private sector clients. Contact the laboratory at 803-896-0810 for more information.

Reporting Schedule

Results are routinely processed for mailing or electronic reporting twice daily. On Fridays and on the last working day before a holiday any reports printed after courier pickup are mailed.

Telephone Results

Panic or Critical Values or Life-Threatening results and/or public health emergencies are telephoned to the appropriate person. A result will not be left on voice mail or an answering machine. A message to call the Bureau of Laboratories for a report will be left.

Copies of Reports:

- 1. Rabies testing: One copy is sent to the sender and one to the county health department.
- 2. Newborn Screening: One copy is sent to the hospital submitting specimen and one to the physician whose name has been entered on the request form. If no attending physician is listed, two copies are sent to the hospital.
- 3. All other tests: One copy is returned to the name entered in the sender section of the request form. We regret that we cannot honor requests for multiple copies. If multiple copies of other test reports are needed, we suggest you photocopy the original report issued.

Remailing of Results Reports

If a physician or clinic to which the patient has been referred requests a copy of a test result, the report will be reprinted with the original sender number and mailed as requested. If, for some reason, you do not receive a report, you may obtain a copy by calling 803-896-0898.

Correcting Reporting Errors

If an error or the possibility of an error is discovered by the laboratory after results have been mailed, the sender will be notified immediately by telephone. The error will be explained and the correct result given. A corrected hard-copy report will be issued with the comment "Corrected Report" at the next printing.

If an error in reporting is discovered by the sender, the laboratory should be notified immediately. The error will be corrected and a corrected report will be mailed. The corrected report will be printed with the comment "Corrected Report".

DISEASE REPORTING

The Code of Laws of South Carolina (1976) Section 44-29-10: Regulation 61-20 mandates that the Commissioner of DHEC is to publish annually a list of diseases to be reported by physicians and laboratories. This list can be found on the internet at scdhec.net/hs/diseasecont/disease.htm.

All communicable disease outbreaks and unusual disease occurrences should be reported so that appropriate control measures can be implemented.